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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/818,990	03/27/2001	D. Wade Walke	LEX-0152-USA	9270

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EXAMINER	
SWOPE, SHERIDAN	
ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 12/27/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/818,990	WALKE ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 6-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant's election without traverse of Invention I, Claims 1-3 in Paper No. 17 is acknowledged. Applicant's cancellation of Claims 4-5 and addition of Claims 6-10 in Paper No 17 is acknowledged. Claims 1-3 and 6-10 are hereby examined.

Specification-Objections

The title is objected to for not being descriptive of the invention. The abstract of the disclosure is objected to because it does not describe the invention sufficiently; the function of the recited proteins should be stated. Corrections are required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 6-10 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. As stated in the specification, the proposed utilities for the polynucleotide of SEQ ID NO: 1 and or the protein of SEQ ID NO: 2 are: microarrays, or other assays; to screen genetic material from patients; identification of mutations associated with SEQ ID NO: 1; diagnostic assays; preparation of oligonucleotides derived from SEQ ID NO: 1; hybridization assays; library screening; analysis of expression patterns; identification of molecular targets; and identification of disease-related mutations (pages 6-8). Each of these utilities is an application which would apply to every member of a general class of materials and/or is a use only for further research to determine a use for SEQ ID NO: 1 or the protein encoded thereby. As such, these asserted utilities are not specific (for those applicable to all human DNAs) or not substantial because the use of SEQ ID NO: 1 and SEQ ID NO: 2 therein is

only potential and not in currently available in practical form. Although the specification recites some homology to a variety of some mammalian muscle protein (page 2, parag 1) it does not disclose a specific utility for the protein encoded by SEQ ID NO: 1 and set forth by SEQ ID NO: 2. Therefore, Claims 1-3 and 6-10 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by a deduced or established utility.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 2 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "hybridizes under stringent conditions" in Claim 8 is a vague and ill-defined term that renders Claims 8 indefinite. The phrase "hybridizes under stringent conditions" is not defined by the claims, the specification does not define said phrase, and within the art this term does not have a clear meaning as the metes and bounds of the term vary depending on the situation and the person using the term. Thus, one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 7, and 10 are rejected under 35 U.S.C. 112, first paragraph. The specification, is enabling for the isolated full-length polynucleotide of SEQ ID NO: 1, which encodes the

motilin-like muscle protein set forth by SEQ ID NO: 2. However, the specification does not reasonably provide enablement for any isolated nucleic acid comprising at least 24 contiguous bases of SEQ ID NO: 1, expression vectors thereof, or host cells thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 1 is so broad as to encompass any polynucleotide sequence comprising at least 24 contiguous bases of SEQ ID NO: 1. Claim 7 is so broad as to encompass any expression vector comprising any polynucleotide sequence comprising at least 24 contiguous bases of SEQ ID NO: 1. Claim 10 is so broad as to encompass any host cell comprising any expression vector comprising any polynucleotide sequence comprising at least 24 contiguous bases of SEQ ID NO: 1. The scope of each of these claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polynucleotides, vectors, and host cells broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the protein's structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence of SEQ ID NO 1 and the encoded polypeptide set forth by SEQ ID NO: 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims,

and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the results of such modifications are unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the Claims 1, 7, and 10 which, encompasses all polynucleotide sequences comprising at least 24 contiguous bases of SEQ ID NO: 1, expression vectors thereof, and host cells thereof. The specification does not support the broad scope of Claims 1, 7, and 10 because the specification does not establish: (A) the activity of any polypeptides encoded by polynucleotide sequences comprising at least 24 contiguous bases of SEQ ID NO: 1; (B) regions of any said polypeptide's structure which may be modified without effecting the activity of said polypeptide; (C) the general tolerance of the activity of said activities to modification and extent of such tolerance; (D) a rational and predictable scheme for modifying any residues with an expectation of obtaining the desired biological function; and (E) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polynucleotide sequences comprising at least 24 contiguous bases of SEQ ID NO: 1, expression vectors thereof, and host cells thereof. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of

sequences having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claims 1, 7, and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a genus of nucleic acid molecules including any number of polynucleotide sequences comprising at least 24 contiguous bases of SEQ ID NO: 1. The specification does not contain a disclosure of the function of all nucleic acid molecules corresponding to sequences comprising at least 24 contiguous bases of SEQ ID NO: 1. The genus of polynucleotides that comprise these above nucleic acid molecules is a large variable genus with the potentiality of encoding many different proteins with a variety of functions or no function. Therefore, many functionally unrelated polynucleotides and polynucleotides without function are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only one species of the claimed genus (SEQ ID NO: 1) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Since Claims 7 and 10 recite expression vectors and host cells comprising said genus of polynucleotides, Claims 7 and 10 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al, 1996. Hiller et al teach the sequence of a nucleic acid molecule that has 100% identity with residues 68-337 of SEQ ID NO: 1 of this application. Therefore, Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al, 1996.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al, 1996 in view of Ausubel et al, 1987 and further in view of Zheng et al, 1990. The teachings of Hillier et al are described above. Hillier et al do not teach a recombinant expression vector containing their nucleic acid molecule or host cells containing an expression vector comprising their polynucleotide. However, it is common in the art to subclone nucleic acid molecules into expression vectors and transfect such constructs into host cells (Ausubel et al, 1987). It would

have been obvious to a person of ordinary skill in the art to use the methods of Ausubel et al to subclone the polynucleotide of Hillier et al into an expression vector and transfect said construct into host cells. The use of the methods of Ausubel et al to make host cells comprising the nucleic acid molecule of Hillier et al is suggested by the fact that said nucleic acid molecule is highly homologous to the BTF3b transcription factor (Zheng et al). One would be motivated to make host cells comprising the nucleic acid molecule of Hillier et al in order to determine whether the encoded protein is a transcription factor. The expectation of success is high as subcloning, transfection, and heterologous expression of proteins are standard in the art. Therefore, Claims 7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hillier et al, 1996 in view of Ausubel et al, 1987.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 703-305-1696. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 703-308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Sheridan L. Swope, Ph.D.

REBECCA E. PRUSTY
PRIMARY EXAMINER
GROUP ~~1600~~
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